MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Individual Safety Report

3142702-3-00-01

McNEIL CONSUMER PRODUCTS COMPANY
FORT WASHINGTON, PA 19034

Page ____ of ____

Approved by FDA on 11/15/93

1 # .

eport #

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
01561264	39 yrs or Date of birth: [redacted]	( )female (X)male	unk lbs or kgs
In confidence			

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

(x) death 10/31/92 (mo/day/yr)
( ) life-threatening
(x) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event: 9/30/92 (mo/day/yr)

4. Date of this report: 10/08/98 (mo/day/yr)

5. Describe event or problem

Notification via litigation of case summaries provided by physician/co-author of literature report (N Engl J Med 1997; 337:1112-7). Info provided based on extracted data from medical records of patients hospitalized for acetaminophen ingestion between 1/1/92 & 4/30/95. According to extracted data, a 39 yo fasting male, w/ hx of previous liver disease, drug use, ethanol use (18-24 beers/day), binging up to 48 ers/d up to 5 days PTA & poor nutrition status, ingested 1500mg q 4 hrs (60 tablets in 72 hrs) of Extra Strength TYLENOL in an ACCIDENTAL OVERDOSE & died. Addl info rec'd 10/1/98: med records indicate following ingestion, pt noted jaundice, fatigue (ASTHENIA), nausea, & coffee ground emesis (VOMITING). On 10/1/92, pt admitted & treated w/MUCOMYST. Progression to LIVER FAILURE, RENAL FAILURE & ENCEPHALOPATHY. On 10/30/92, pt had HEART ARREST during hemodialysis. Pt resuscitated & intubated. On 10/31/92, life prolonging measures were d/c & pt expired (DEATH). PM exam revealed:end stage cirrhosis exacerbated by acetaminophen toxicity.

6. Relevant tests/laboratory data, including dates

9/30/92: Creat=1.9, BUN=41, AST=3760, ALT=1920, AP=167, t. bili=12.8, GGT=537, acetaminophen level=57, PT=47.9, PTT=64.4; 10/1/92 HBsAg=(-), a-HBc=(+), a-HBC IgM=(-), a-HCV=(+), TP=5.9, Alb=2.4, globulin=3.5, (See Sect B7)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

hx of tatoo, hx of hepatitis B 13 yrs PTA, former intravenous drug abuser, long hx of chronic ethanol abuse (drank 18-to-24 beers a day for 20-years), family hx (+) for chronic alcoholism; NKDA Sect B6 con't: A/G ratio=0.7; '2/92 NH3=122; 10/31/92 WBC=23.7, HGB=9, HCT=26.6, t=115, CPK=1434, CK-MB=20, CK-Index=14, (See Sect C10)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Extra Strength TYLENOL product

#2

2. Dose, frequency & route used

#1 up to 30 grams, po

#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 9/27/92-9/30/92; 72 hours

#2

4. Diagnosis for use (indication)

#1 headache

#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)

#1 Unknown

#2

7. Exp. date (if known)

#1 Unknown

#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

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10. Concomitant medical products and therapy dates (exclude treatment of event)

none Sect B.7 con't: PT=46.3, PTT=93.9, Creat=12.6, BUN=56, 11/1/92 path lab-principal diagnoses: (1)end stage liver dx w/(a)active micronodular cirrhosis, (b)intrahepatic cholestasis, (c) multifocal centrinodular hepatocellular necrosis

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
( ) consumer
(X) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr): 10/01/98

5. (A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
( ) Initial (X) follow-up # 1

8. Adverse event term(s)

OVERDOSE ACCID
ASTHENIA
LIVER FAILURE
ENCEPHALOPATHY
DEATH
VOMITING
KIDNEY FAILURE
HEART ARREST

9. Mfr. report number: 0906179A

E. Initial reporter

1. Name, address & phone #

[redacted] MD
[redacted] Medical Ctr
[redacted]

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2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	physician	( ) Yes ( ) No (X) Unk

FDA

Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.